1st Bridge Health Meeting of the EUBIROD NETWORK

Hotel Archimede, Via Dei Mille 19, Rome, Italy

23–24th November 2015

Minutes of the Meeting

Agenda items:

1. THE BRIDGE HEALTH PROJECT
2. PARALLEL SESSIONS
3. STATE OF THE ART AND POTENTIAL IMPROVEMENTS
4. BRIDGING ACTIVITIES

Participants: Massimo Massi Benedetti (**MMB**; HIRS, Italy; Chair); Concetta Tania Di Iorio (**CTDI**, Serectrix, Italy), Inbar Zucker (**IZ**; The Israel Center for Disease Control, Israel); Iztok Štotl (**IS**; University of Ljubljana, Slovenia); Scott Cunningham (**SC**; University of Dundee, Scotland, United Kingdom); Tamara Poljicanin (**TP**; Croatian National Institute of Public Health, Croatia); Fabrizio Carinci (**FC**, University of Surrey, England United Kingdom), Debbie Cooke (**DC**, University of Surrey, England United Kingdom), Vivie Traynor (**VT**, Ministry of Health of Cyprus, Cyprus), Ilmo Keskimaki (**IK**, THL, Finland), Sándor János (**SJ**, University of Debrecen, Hungary), L.Uccioli (**LU**, Università Tor Vergata, Italy), Stefano Gualdi (**SG**, Italy), Domenico Mannino (**DM**, Ospedale di Reggio Calabria, Italy), Gaia Mannino (**GM**, Ospedale di Reggio Calabria, Italy), Simona Giampaoli (**SI**, Istituto Superiore di Sanità, Italy), Saverio Stranges (**SS**, Luxembourg Institute of Health, Luxembourg), Joanna Polanska (**JP**, Silesian University of Technology, Poland), Simion Pruna (**SP**, Telemedica Consulting, Romania), Joan Marc Servitja (**JMS**, IDIBAPS, Spain). Stella de Sabata (**SdS**. IDF Europe, Belgium).

Apologies: Fred Storms (Netherlands), Wil Kujipers (IVZ, Netherlands), Joseph Azzopardi (University of Malta, Malta), Kris Doggen (WIV-ISP, Belgium), Jana Lepiksone, Liene Golosujeva (MoH, Latvia), Karianne Loevaas (NOKLUS, Norway), Michael Jecht (Havelhöhe, Germany), Peter Beck (Joanneum Research, Austria), Sofia Gudbjörnsdottir (National Diabetes Register, Sweden), Przemka Jarosz-Chobot (University of Silesia, Poland), Natasa Bratina (University of Ljubljana, Slovenia), Attila Nagy (University of Debrecen, Hungary), Zeliko Metelko (University of Zagreb, Croatia), Gerard Boran, Tony Moulton (Adelaide Hospital, Ireland), Peter Rossing (Steno, Denmark).

Minutes prepared by:
Fabrizio Carinci, University of Surrey
20th January 2016

SESSION 1. BRIDGE HEALTH WORKPACKAGE 8

1. THE BRIDGE HEALTH PROJECT

FC presented the conceptual framework of **Population–based Disease Registries** as the theoretical basis for Workpackage 8 of Bridge Health:

- According to the PARENT Joint Action Guidelines[1]:
  - P**atient registry** is „*... an organized system that collects, analyses, and disseminates the data and information on a group of people defined by a particular disease, condition, exposure, or health-related service, and that serves a predetermined scientific, clinical or/and public health (policy) purposes*".
  - **Disease or condition registries** „*..are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure, or the same group of conditions such as disability.*". Here EUBIROD is explicitly mentioned as: „*..as an example of an EU project/initiative concerning improving disease registries in terms of defining purposes, legal context, semantic and technical aspects..Overall, EUBIROD can serve as a good example and model to be re-used for other chronic diseases as well*".
  - **Population Registry** „*... is a registry that intends to cover all residents in a given geographic area within a given time period. The coverage of the specific registry may, however, be incomplete, but it is nevertheless a population registry if the aim is to include all the individuals in the target population. A population is defined by geographical boundaries, but usually only residents (or citizens)within a given time period are included in the definition.*".
  - **Population–based registry** should be used "*...when all persons with a given trait, exposure or event, are intended to be included in the registry. If the registry includes everyone in the population (even the oldest), it becomes a population registry. Intention rather than performance defines the terms. A population-based disease registry aims at including everyone with the disease in the population, be it self-reported, clinically diagnosed or detected at screening. Population and population-based registries may be further classified as of good or bad quality depending on coverage or other characteristic*s".
- The conceptual framework of EUBIROD emerged as a common structure derived from existing implementations in Europe[2].
  - a regional population-based disease register has been identified as the gold standard allowing to compute accurate numerators (eg absolute number of major amputations in people with diabetes) on top of well defined, area based denominators (eg the total number of people with diabetes in a specific territorial area eg catchment area, province or region).
  - population-based registries can transform databases into actionable information for policy makers, health professionals and citizens. The idea of „essential levels of health information"[3] originated from the early experience of the BIRO project and may be useful in general and more specifically for Task 8.2 in Bridge Health.

SI presented the general features of the Bridge Health project and the specific aims of Workpackage 8 for the 'Platform for population based registries':

- Bridge Health originated in reply to the call action 2.1.3.3. "Towards a sustainable health monitoring and reporting system", priority 2.1.3. "Actions under thematic priority 3 – Contributing to innovative, efficient and sustainable health systems in the Work Programme 2014 of the Public Health Programme of Community action in the field of health (2014-2020)".
- The proposal aimed at ensuring sustainability of health information under the past EU frameworks and enhance synergy among activities. The project targets the unequal access to health information and the delivery of accurate results of regional variation for selected population groups. Outputs will be mainly blueprints for a sustainable and integrated EU Health information system, standardizing data collection and exchange, procedures for internal and external validation of health indicators, priority setting and ethical and legal issues.
- A Steering Committee Meeting of the Bridge Health project has been held on 6th-7th October 2015 to discuss the general conceptual framework of the EU Health Information System as specifically requested by the European Commission.
- The specific aims of WP8 **'Platform for population based registries'** are:
  1. to gather and harmonise methods and best practices of population-based registries;
  2. to improve standardisation and quality of data collection;
  3. to facilitate implementation, sustainability, and maintainance;
  4. to provide community health indicators of occurrence, quality of care and outcomes
- A population based register is intended to cover all residents in a given geographic area within a time period, including all events of a specific disease to monitor its occurrence. This would help understanding the differences and changes in the natural disease dynamics, as well as identifying vulnerable groups and highlighting the various consequences of the disease, including the utilization of services eg diagnostic tools and treatment.
- Task 1 aims to create a network of experts in population based registries in charge of identifying standardised definitions, common procedures and methods to establish population based registries (particularly to deliver ECHIM indicators). A dedicated EUPHA workshop was conducted in Milan on the 17th Oct 2015 to discuss standardization and quality issues.
- The Bridge Health project also includes Horizontal Activities (HAs) bringing together the expertise developed within specific health information domains to tackle:
  1. transferability of health information and data for policy;
  2. unequal access to health information;
  3. enhanced regional data for specific groups;
  4. standardised methods for the collection and exchange health information;
  5. identification of data quality assessment methods including internal and external validation of indicators (particularly relevant for WP8)
  6. methods for priority settings; and g) harmonisation of ethical and legal issues.

MMB presented **WP 8 Task 2** in more detail.

- The main aim of the task is 'to maintain and strengthen the implementation of population based registries for chronic diseases through the standardization of methodologies for producing standardized EU-wide indicators, taking selected clinical conditions as test cases for a new 'platform for population based registries'.
- A specific objective will be the provision of privacy-enhanced software for statistical analysis, data exchange, and automated calculation of indicators, locally and at EU level.
- This task will take advantage of the continuing EUBIROD network of registers, coordinated by HIRS, to make further progress and deliver results across different diseases.
- The further development of the open source software for data management, statistical analysis and automated delivery of indicators will be facilitated through a user friendly interface enabling data custodians to produce local reports and to transmit data towards a central location for the routine production of EU indicators (e.g. ECHI shortlist). Compliance of the whole process with privacy and data protection rules will be supervised by targeted evaluation methods, made available to participating registers. Development of technical manuals will be also included, taking into account sets of recommendations for personnel involved in data processing of population-based registers.
- Deliverables include: MS32 (Tor Vergata): 8.2 Blueprint of open source platform for population-based chronic disease registers (draft), at month 18; MS33 (Tor Vergata): 8.3 Manual of technical specifications for users and programmers (draft), at month 18; MS35 (Tor Vergata): 8.5 Blueprint of open source software platform for population-based chronic disease registers (final) and MS36 (Tor Vergata): 8.6 Manual of technical specifications for users and programmers (final) at Month 30.
- Key personnel involved in this work will be MMB, FC, LU, CTDI, and SG. They will seek advise and coordinate results received from across the whole EUBIROD network.

LU presented the topic of **Optimizing EUBIROD reports for routine clinical practice**, particularly focusing on the point of view of clinicians and caregivers:

- Clinicians and caregivers in chronic diseases require information:
  a) to make decisions
  b) to know expected outcomes
  c) to inform patients
  d) to evaluate performance
- Clinicians need 'comparable data' rather than numbers. In this perspective, task 8.2 should strive to define a robust European data dictionary where proper clinical definitions can be used to analyse diabetes outcomes and provide the core elements for data collection from existing electronic health records.
- The EUBIROD core standards published in a recent paper[4] respond to these criteria for diabetes, but it is still important to drill down in relation to specific complications, eg not just retinopathy but background/proliferative retinopathy.
- The task should explain how to merge individual characteristics with relevant clinical information, i.e. age and duration of the disease plus metabolic control, type of therapy and presence of other comorbidities. Increased depth may allow generating outputs of utmost interest eg risk tables similar to the UKPDS risk engine, cardiac risk assessment, etc.

2. PARALLEL SESSIONS

Session A (TECHNICAL). Revising the BIRO approach

Participants: SG, IS, FC, SC, SP

SG introduced the main advancements required in the definition of Task 8.2 '**Blueprint of open source software for population-based chronic disease registers':**

- main goal to be fast, user friendly, extensible and simple to program
- minimize dependencies from other software (minimal need to install other packages)
- multiplatorm, installed directly in each operating system (without virtualization)
- configurable input data stream (amenable to be customized to different diseases)
- data entry and quality control optional outside the main program
- not including ETL data transformation (performed by other specialized software)
- allowing both local and central analysis
- internationalization module built in
- embedding simple data transmission module

The above points can be successfully trialled through the further adaptation of a prototype named 'NEO', which has been specifically realized to overcome the main bottlenecks experienced in BIRO.

IS introduced the main issues to be included in the **Manual of technical specifications for users and programmers** (a document including an outline of the index has been delivered in advance of the meeting):

- short general information (web format)
- data requirements and preparation (ETL)
  - Information on merge table, population, activity, etc.
- quality issues (clarifications of restrictions for data use)
- legal issues for data privacy (including assessment criteria) explained in short
- structurally linked to meta-registry (eg BIRO-tunes):
  - Indicator web repository of draft, approved and domain specific indicators
- possible implementation of a EUBIRO-Developers YouTube Channel

For the Technical Work to be carried out in Task 8.2, the panel finally agreed:

A. to consider data linkage out of scope in this project

B. to design and document:

1. a simple tool to convert the XML ('Core Standards' paper) to a NEO import specification file
2. simple data quality checks in NEO
3. format of data outputs of the statistical engine to be transmitted to the common server
4. communication protocols between the local client and central server (eg FTP, SSH, etc)
5. organization and governance of the central server

A feasible subset of any of the above tools will be specifically developed to demonstrate the functionality of all modules. Routines will be integrated into a newly redesigned BIRO software, to be trialled in a test data collection adopting only a minimal number of indicators (see other panels).

The above work shall lead to a first draft deliverable by Month 18 (November 2016)

Session B (LEGAL). Revising the Privacy Assessment

Participants: CTDI, SI, IK, JP, SJ, SdS, DM, GM

CTDI introduced the principles at the basis of a **consolidated "Privacy & Ethics Impact and Performance Assessment" (PEIPA) of EU linked data and disease registries**.

The methodology builds upon a further elaboration of the experiences made for the Privacy Impact and Performance Assessment conducted in the BIRO[5] and EUBIROD[6] projects. The new method is aimed at evaluating different alternatives in the further refinement of the architectures proposed by relevant Bridge Health networks. By no means, the methods is aimed at scoring, classifying or ranking the different Consortia according to principles of Privacy and Ethics.

Five consecutive steps are envisaged in the proposed process:

1. Acquisition of standardized information (data sources, data flow, etc) regarding the architectures of EUBIROD, ECHO and EUROHOPE (3E). Definition of privacy and ethical principles embedded in the data systems.
2. Design of specific questionnaire and derived scoring system (Q-PEIPA) to evaluate 3E [This questionnaire should be build upon previous experiences, updated and expanded to consider data governance mechanisms. It should be administered to data manager seeking legal advise. A Webinar may be considered to help the process. Translation in local languages shall also be considered]. Establishment of an ad hoc PEIPA Advisory Panel of Experts (PEIPA-APE). Submission of the Q-PEIPA to the 3E Consortia and data collection finalized.
3. Quali-quantitative analysis of collected data. Submission of a draft report to the PEIPA-APE.
4. Preparation and conduction of a plenary PEIPA Meeting for collegial discussion
5. Identification of best practices to benchmark privacy and ethics in the 3E. Delivery of the final report as a chapter on Privacy Impact Assessment in the final WP11 report.

For the Legal Work to be carried out in Task 8.2, the panel agreed:

- for CTDI to coordinate the proposed process
- inclusion of all participants in an ad hoc Ethics and Privacy Organizational Panel designed to support the coordinator and the foreseen PEIPA-APE.
- Initial composition of the PEIPA-APE (to be confirmed): David Smith (former Privacy Commissioner of the UK), Paivi Hamalainen (THL, Finland), Dorotea De Marco and Manuela Siano (Italian Privacy Authority), Jillian Oderkirk (OECD Health Division, France)
- a proposed time schedule for the entire process to be completed as follows:
    - Step 1: M7-M11 (**Principles set by March 2016**)
    - Step 2: M12-M17 (**Questionnaire data collection by September 2016**)
    - Step 3: M18-M20 (**Draft Report by December 2016**)
    - Step 4: M21-M22 (**Task Meeting by February 2017**)
    - Step 5: M23-M30 (**Final Report by October 2017**)

Session C (CLINICAL). Revising the Clinical Use of EUBIROD reports

Participants: TP, MMB, IZ, DC, VT, LU, SS, JP, JMS

TP introduced the topic of k**ey indicators for targeted EUBIROD reporting**, highlighting the current strengths and weaknesses of the BIRO system:

- the existing report has strengths and weaknesses that partially overlap and need to be taken into account while revising indicators in the proposed template format.
- BIRO reports are very detailed and stratified according to type, gender, age groups, duration of diabetes while results are presented through tables, box plots, Trellis Bar plots, and box and whisker plots.
- for epidemiological outputs eg chi-square test, too many cells have zero observations and there are just too many comparisons tested to provide summary results
- comparisons between countries and risk-adjusted indicators are available and can be very useful

For the Clinical Work to be carried out in Task 8.2, the panel finally agreed:

- **to define the structure of simplified 'basic reports'** with a more specific clinical orientation (for local reports), or presentation of national disease indicators for policy making and continuous monitoring. These reports should specify which portion can be attributed to the use of administrative data or clinical registries, and according to strata by health care level.
- **to make clinical reports more targeted and** dynamic, for instance by using simple association measures eg Odds Ratios that could better inform clinicans, or by making more specific queries possible for the clinician
- **to deliver:**
  - all indicators previously included in BIRO in NEO (keeping mandatory items)
  - new basic reports using only a subset of indicators specified in the manual (Nov 2016)
  - scientific paper using data from 2010 to be submitted by end February 2016
  - new data collection finalized within 2016
  - new indicators eg socio-economic status (using level of education as a proxy)

SESSION 2. THE EUBIROD NETWORK

3. STATE OF THE ART AND POTENTIAL IMPROVEMENTS

FC introduced the issue of **Updating the BIRO data collection**:

- The latest EUBIROD data collection has been undertaken in 2012. On 8/2/2012 a new BIRO Release 2.1.12 was deployed to partners, who used it to deliver all aggregate data (statistical objects) by 15/2/2012. The central analysis was carried out in the following week, resulting into a EU report including 79 indicators on 21/2/2012.
- Discussions undertaken at the final EUBIROD meeting in Cyprus (March 2012) did not support the presentation of a formal report. It was perceived that the heterogeneity of data did not sufficiently represent quality of care in Europe. In fact, the number of subjects collected by EUBIROD partners ranged between 161-54,064 out of a total of 199,902, and the availability of BIRO Indicators between 21-78, out of a total of 79.
- However, following the publication of the core EUBIROD standards, partners meeting in Surrey in August agreed that a paper showing the capacity of the network to populate the diabetes information framework could have been meaningful. Consequently, a scientific paper[7] has been drafted and was generally discussed with participants at the meeting. The paper also included risk adjusted diabetes indicators and diabetes complications.
- Comments from partners approved the format of the paper, suggesting relevant changes:
  - rather than 'diabetes registers' use the term 'data sources'
  - data should be presented by type and capacity of data sources (eg separating results between 'clinical databases' and 'population-based diabetes registers')
  - emphasis should be given to correlation rather than absolute values (eg sensible increasing risks by age and duration of diabetes), showing the ability of the system to collect meaningful results.

Partners agreed on a possible update of the data collection, using a revised tool that could be more flexible in Bridge Health:

- it was agreed that the development of new software was out of scope, as the blueprint was the major task to be performed. In this regards, EUBIROD has already a lot to pass on to other networks in terms of systematic documentation of the approach.
- nevertheless, a more flexible tool could be made available to undertake a scaled down data collection, consistently with the above guidelines. **SG** has explained how to adapt this tool to the new data collection
- the critical issue was to identify the set of core variables to be collected. Building upon the slides presented by **LU** from the core standard paper, the EUBIROD network agreed to collect the following variables: those included in the upper right quadrant of Figure 2, plus the borderline ones: 'Smoking Status', 'Systolic Blood Pressure', 'Foot examination' and 'Amputation'
- if successful, the process should be repeated annually to consolidate a publication eg the 'Annual EU Diabetes Report'

S.Cunningham (U.Dundee) discussed the possibility of a **Large scale Implementation of "My Diabetes My way"** (MDMW):

- MDMW[8] is a website for patients and carers. It includes all necessary information eg information leaflets, interactive content, videos, patient testimonials etc. Its content has been validated through the supervision of a multidisciplinary group that includes also patients, healthcare and Itprofessionals.
- The development of MDMW is consistent with the recent literature, including RCTs showing that '*patients preferred computer systems that provided information from their medical records to systems that just provided general information*'[9].
- MDMW shows doctors and patients grouped and personal results obtained for major diabetes indicators. The system has solid privacy and data protection rules enabling only accredited subjects to access sensitive data.
- MDMW Personal Health Record is limited to key diabetes data, i.e. information explaining clinical measurements. It includes feedback processes to report errors and a full system audit trail. It has been live since december 2010 and is available to anyone with diabetes in Scotland. The andecdotal feedback received by patients has been very positive, particularly for self-management (eg 'It is great to be able to view all of my results so that I can be more in charge of my diabetes...').
- The success reported in Scotland may underpin a potential interest in extending this application beyond the national borders to serve the information and care needs of other countries. The system may be implemented in diabetes first, but then could be generalized to diabetes complications eg cardiovascular diseases, renal diseases and other co-morbidities. Its construction on top of routine standardized population-based databases eg the one envisaged in BIRO may well adapt to the general framework of Bridge Health.
- The importance of the system may spread beyond the usage of health information, since it can represent a solution to engage citizens as active participants in their own care, sharing data with care providers for integrated care. This way it will be possible to provide advice tailored to the patient.
- The system supports enhanced telehealth and telecare through data integration, as it can link to applications for home recorded weight, blood glucose, BP, etc eg activity and lifestyle wearable sensors, diet/exercise planning from smartphone apps and in-built sensors to aid medication concordance

The audience agreed that MDMW may be considered as a new platform for an active use of health information:

- it can be included in the documentation linked to Bridge Health, as a way to enable data sources to directly engage service users, improving their satisfaction, empowering them and promoting active and healthy ageing
- to make this possible, new projects can extend the current platform to other countries and beyond the state of the art, designing new tools for self management, creating open APIs allowing to interact with third-parties, developing data analytics, modelling, and visualisation, and assessing privacy impact and readiness for a healthcare service of this type
- The advantages of such a new model should be formally evaluated in different settings, using a proper scientific design eg a cluster multicentre RCT.

Debbie Cooke (U.Surrey) introduced the issue of P**atient Reported Outcome Measures (PROMs) in Diabetes:**

- PROMs are usually derived from standardised, validated questionnaires completed by patients to assess different health constructs. In general, a PROM would be any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else
- PROMs are constructs that may capture different aspects eg Functional status, Well-being
- Quality of life, Impact of condition or its treatment, Symptoms, Distress etc.
- PROMs are becoming increasingly important because they represent a unique patient perspective, which captures information that is not observable, and in some cases may be more important than clinically observable information.
- It has been shown that PROMs have often better prognostic value than standard, clinical measures. Evidence shows that clinicians have limited ability at detecting aspects eg emotional distress and depression; tend to underestimate symptoms, particularly those that are harder to observe clinically – ultimately, PROMs have shown to well predict mortality: questionnaires have beated physical tests.
- Study applications today range from RCTs on clinical and cost-effectiveness, to monitoring symptoms, facilitating communication between patients and clinicians, commissioning services and drug/treatment approval. However, the importance of PROMs today is increasing even for their use in performance evaluation and public reporting: they have become mandatory in several clinical areas in the UK and are now being introduced even in quality registries (eg Denmark and Sweden) to report on health services performance.
- Some methodological aspects are key in the selection and usage of PROMs eg psychometric properties, internal reliability (consistency), test-retest reliability, content validity, sensitivity or responsiveness to change (minimally important difference)
- An important choice to be made in each case is whether a selected PROM should be generic or disease-specific.
- The current evolution towards high level interaction with individual subjects using mobile applications has led to the development of ePROMs: these may have the benefits of rapid data collection, less missing data, easier and quicker input and storage of data and reduced cost
- Current problems include the cost of data collection, which may be too high for routine cycles in limited healthcare settings, as well as privacy and data security, given the amount of transactions triggered by telematic applications.

The network agreed that the introduction of PROMs will represent an important element in the future evolution of clinical registries:

- certainly the inclusion in the EUBIROD core standard would be costly, complex and inappropriate in the short term. However, it could be possible to trial their use in settings that are introducing PROMs data collection at an experimental level (eg Sweden and Denmark).

- PROMs may represent an ideal endpoint for new RCTs introducing new systems of care, including new organizational arrangements, payment schemes, or novel information tools eg MDMW.

SESSION 3. INFORMATION AND RESEARCH FOR POLICY AND PRACTICE

4. BRIDGING ACTIVITIES

A thorough examination of the funding schemes available at the international level was conducted, with a view to bridging current activities with the future evolution of population-based registries. In particular, the network examined the EU programmes with reference to diabetes.

In relation to Public Health (DG SANCO) funding options, it was noted that:

- topics aimed at the optimisation of health services for EU citizens are scarce. The latest programmes still show a disease-oriented approach that does not relate to diabetes or people with chronic diseases. Focus on prevention in the general population make relevance of disease registries very limited
- there is no Joint Action specifically designed for population-based registries
- only option for a network of disease registries eg EUBIROD are 'operational grants' which provide limited funding for coordinating entities

In relation to ICT funding options, it was noted that:

- they mainly relate to low level engineering solutions eg robots or wearable systems, increasingly distinct from software innovation and development, as well as the engineering of health information systems and integrated services.

In relation to Horizon 2020 Health Research Programe, it was noted that:

- the program is mainly devoted to personalized medicine, which represents only a very limited portion of the actual range of applications potentially emerging from the scenario of patient registries
- the only relevant topics would be those calling for new systems of care which may also include targeted combination eg BIRO+MDMW with diabetes indicators and also PROMs envisaged as outcome measures, whose advantages can be formally tested against results obtained with ordinary care
- the pathway for the definition of a potential ERIC on health information is still completely unclear

The network agreed that:

- the European Union currently does not offer many opportunities for R&D allowing a practical implementation of the concepts delivered for population-based registries in Bridge Health
- this casts an enormous problem regarding the utility and timeliness of the solutions proposed in this project: while experts still discuss about the information needs, potential working solutions are overlooked and the problem of chronic diseases is increasing exponentially
- there is a need to make a strong case at all levels in the EU (MEPs and Directorates of the European Commission). Stakeholders shall be made aware that there is a need to push for resourcing instruments that would allow testing and implementing solutions that can bring substantial benefits to EU citizens.

REFERENCES

1. PARENT Joint Action Guidelines, http://patientregistries.eu/documents/10184/14613/Methodological+guidelines+and+recommendations+for+efficient+and+rational+governance+of+patient+registries/5bf3ea46-26ca-4d91-b459-47dce18a8846
2. Carinci F, Di Iorio CT, Massi Benedetti M, Standardized information exchange in diabetes: integrated registries for governance, research and clinical practice, in Bruttomesso D, Grassi G (eds), Technological Advancements in the Treatment of Type 1 Diabetes, Front Diabetes, Basel, Karger, vol 24, 1-14, 2014.
3. Carinci F. Essential levels of health information in Europe, Health Policy. 2015 Apr;119(4):530-8.
4. Cunningham SG, Carinci F, Brillante M, Leese GP, McAlpine RR, Azzopardi J, Beck P, Bratina N, Boucquet V, Doggen K, Jarosz-Chobot PK, Jecht M, Lindblad U, Moulton T, Metelko Ž, Nagy A, Olympios G, Pruna S, Skeie S, Storms F, Di Iorio CT and Massi Benedetti M, Defining a European diabetes data dictionary for clinical audit and healthcare delivery: core standards of the EUBIROD project, Methods of Information in Medicine, 2015 Dec 15;55(2).
5. Carinci F, Azzopardi J, Storms F, Cunningham SG, Beck P, Pruna S, Skeie S, Lepiksone J, Gualdi S, Brillante M, McAlpine RR, Perner P, Stotl I, Di Iorio CT, Bratina N, De Beafourt C, Boucquet V, Doggen K, Jarosz-Chobot PK, Polanska J, Jecht M, Lindblad U, Aberg M, Moulton T, Boran G, Metelko Ž, PolijicaninT, Nagy A, Ianos S, Olympios G, Traynor V, Evripidou A, Lovaas K, Tysse T, Canivell S, and Massi Benedetti M, Automated cross-border reporting of standardized quality of care and outcomes indicators: results of the EUBIROD project from nineteen diabetes registers, *In preparation*
6. Di Iorio CT, Carinci F, Azzopardi J, Baglioni V, Beck P, Cunningham S, Evripidou A, Leese G, Loevaas KF, Olympios G, Orsini Federici M, Pruna S, Palladino P, Skeie S, Taverner P, Traynor V, Massi Benedetti M, Privacy impact assessment in the design of transnational public health information systems: the BIRO project, Journal of Medical Ethics, Dec;35(12):753-61, 2009.
7. Di Iorio CT, Carinci F, Brillante M, Azzopardi J, Beck P, Bratina N, Cunningham SG, De Beaufort C, Debacker N, Jarosz-Chobot P, Jecht M, Lindblad U, Moulton T, Metelko Ž, Nagy A, Olympios G, Pruna S, Røder M, Skeie S, Storms F, and Massi Benedetti M, Cross-border flow of health information: is "privacy by design" enough? Privacy performance assessment in EUBIROD, Eur J Public Health. 2013 Apr;23(2):247-53.
8. Cunningham S, McAlpine R, Leese G, Brennan G, Sullivan F, Connacher A, Waller A, Boyle DI, Greene S, Wilson E, Emslie-Smith A, Morris AD. Using web technology to support population-based diabetes care. J Diabetes Sci Technol. 2011 May 1;5(3):523-34.
9. Jones R, Pearson J, McGregor S, Cawsey AJ, Barrett A, Craig N, Atkinson JM, Gilmour WH, McEwen J. Randomised trial of personalised computer based information for cancer patients. BMJ. 1999 Nov 6;319(7219):1241-7.